

**“Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years”
Key Messages / DRAFT 1 / May Contain Errors of Fact or Omission**

Overall Messages

- **A comprehensive and thorough study-- designed and interpreted with extensive input from independent outside consultants;** 42 neuropsychological outcomes were assessed, including measures of speech and language skills, fine motor coordination and intelligence. Among others, advice and input was provided by twelve consulting psychologists and six external consultants.
- **The study did NOT assess autism as a possible outcome of thimerosal exposure through vaccination.** CDC is conducting a separate autism case-control study to specifically evaluate possible associations between thimerosal and autism.
 - According to research published to date, neither thimerosal-containing vaccines nor the Measles-Mumps-Rubella vaccine are associated with increased rates of autism and autism spectrum disorders.
 - Autism wasn't included for a couple of reasons- one, the study was designed to look at other neuropsychological outcomes to assess whether any associations may exist with those types of developmental outcomes.
 - Two, autism and ASD would have entailed a much different methodology (e.g., this study involved the administration of standardized tests).
 - Three, CDC has other studies underway designed to look specifically at autism and ASD and thimerosal.
- **A transparent process from beginning to end;** in addition to the engagement of outside experts and advocates, the dataset used in this study is being made publicly available. Other researchers interested in assessing the data used here can do so. The panel of independent external consultants advised the study design, selection of the neuropsychological test battery, interpretation of results, and editing of the draft manuscript. The consultants have expertise in the fields of toxicology, epidemiology, biostatistics, psychology, vaccine safety, and also included a representative from the autism advocacy community. The external consultants provided their individual input into the study protocol and the analysis plan.
- **Findings are consistent with previously published research.** It provides additional evidence that the low concentrations of thimerosal used as preservative in some vaccines have not caused any harm other than minor reactions such as redness or swelling at the vaccination injection site.
- **Findings are reassuring** – The weight of evidence in this comprehensive study does not support a causal association between early exposure to mercury from thimerosal-containing

vaccines and immune globulins and neuropsychological functioning at the age of 7-10 years. The few statistically significant associations that were detected were small, and were almost equally divided between positive and negative effects. Further, the overall pattern of results suggests that the statistically significant associations may have been chance findings stemming from the large number of statistical tests that we performed (e.g., it would be expected that about 5 percent of the 378 statistical tests—or about 19 tests—would be statistically significant by chance alone).

- Among the 378 statistical tests presented in the manuscript, there were 12 associations where increased exposure to thimerosal was associated with better outcomes and 7 associations where increased exposure to thimerosal was associated with poorer outcomes.
- **One finding, related to motor and phonic tics in boys, may suggest a need for further study. The results reported here were similar to findings in two previously published studies.**
 - Association was only found for males.
 - **Motor and phonic tics are movement abnormalities that are the result of dysfunction in the basal ganglia of the brain. The neuropsychological tests reported otherwise in this study are tests of cerebral cortex function within the brain (language and social skills).**
 - **CDC's National Center for Birth Defects and Developmental Disabilities, which did not participate in this study, is now reviewing the data and will work with experts in the field of pediatric neurology and advise the CDC's Immunization Safety Office regarding possible further analysis of the data, and any other steps that might be indicated to evaluate the potential association with tics.**
- **These outcomes were selected for the following reasons:**
 - Follow-up to the Thimerosal Screening Study, *Pediatrics* 2003
 - Findings from the methyl mercury fish studies
 - Based on input from the external consultants
- **It's important to remember that today, with the exception of some influenza (flu) vaccines, none of the vaccines used in the U.S. to protect preschool children against 12 infectious diseases contain thimerosal as a preservative.** Many vaccines, including the Measles-Mumps-Rubella and chickenpox vaccine never contained thimerosal, and there are preparations of influenza vaccine that do not contain thimerosal as a preservative. As a precautionary measure designed to help reduce children's exposure to mercury from all sources, the U.S. Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agreed in July 1999 that thimerosal should be reduced or eliminated from vaccines where feasible. Vaccines were one of the few sources of any form of mercury where such action could be taken.

- **CDC is fully committed to the health and well-being of children.** Our highest priority is to protect the health of children and to ensure that all children can live, play and learn to their fullest potential. The complexity of the issues and limitations of science and understanding can be frustrating to parents of children with ASDs who continue to seek answers to questions not easily answered. We have learned a lot about the symptoms of autism spectrum disorders (ASDs) and have improved efforts to track the disorders, but we still don't know a lot about the causes of ASDs. Scientists think that both genes and the environment play a role, and there might be many causes that lead to ASDs.
- **CDC places a high priority on vaccine safety and the integrity and credibility of its vaccine safety research.** This commitment not only stems from our scientific and medical dedication, it is also personal--for most of us who work at CDC are also parents and grandparents. And as such, we too, have high levels of personal interest and concern in the health and safety of children, families and communities. We simply don't know what causes most cases of autism, but we're doing everything we can to find out.
- **It is important to remember, vaccines protect and save lives.** Vaccines protect infants, children and adults from the unnecessary harm and premature death caused by vaccine-preventable diseases.
- **Infants and children should receive recommended vaccines on time – doing so protects children from potentially serious and life-threatening illnesses.**

Infant and Environmental Exposures to Thimerosal and Neuropsychological Outcomes at Ages 7 to 10 Years

CDC conducted the *Infant and Environmental Exposures to Thimerosal and Neuropsychological Outcomes at Ages 7 to 10 Years* study to investigate possible associations between prenatal and early childhood exposure to thimerosal-containing vaccines and/or immunoglobulins and deficits in neuropsychological functioning. In addition to neuropsychological testing, data from screening questions regarding tics (a movement disorder) were included in the analysis. Thimerosal is a preservative that contains ethyl mercury and is used in some vaccines and immunoglobulins. This study was not designed to assess possible association between thimerosal and autism.

This study was designed to improve upon previous studies that assessed the possible association between ethyl mercury exposure from thimerosal-containing vaccines and neuropsychological functioning including an objective and prospective measurement of neuropsychological functioning. These improvements reduced the potential for study biases.

The study was further strengthened by engaging a panel of independent external consultants to advise on the study design, selection of the neuropsychological test battery, interpretation of results, and editing of the draft manuscript. The consultants have expertise in the fields of toxicology, epidemiology, biostatistics, psychology, vaccine safety, and also included a representative from the autism advocacy community. The external consultants provided their individual input into the study protocol and the analysis plan.

The study evaluated 1,047 children between the ages of 7 to 10 years who received vaccines during the 1990s when thimerosal was used as a preservative in many childhood vaccines. The study used a retrospective cohort design although outcome measures were collected prospectively. Computerized medical records were used to select a sample of children with a wide range of exposures from thimerosal-containing vaccines and immunoglobulins during infancy. Each child's level of exposure to ethyl mercury was determined through a review of electronic immunization registries, medical records, personal immunization records, and parent interviews. Each child was then administered a series of standardized neuropsychological tests in a clinical setting at ages 7 to 10 years.

One finding, related to motor and phonic tics in boys, may suggest a need for further study.

The study found only a few statistically significant associations or consistent patterns between exposure from thimerosal and neuropsychological functioning. The weight of the evidence from this study does not support an association between early ethyl mercury exposure from thimerosal-containing vaccines and/or immunoglobulins and neuropsychological functioning at ages 7 to 10 years.

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